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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/559,344	04/27/00	NEGRIER	06478.1442

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HM22/0905

EXAMINER
SCHNIZER, H

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/559,344

Applicant(s)

NEGRIER ET AL.

Examiner

Holly Schnizer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. The Preliminary Amendment filed July 31, 2001 (Paper No. 4) has been entered.

Claims 1-7 are pending.

Drawings

2. The drawings have been approved by the draftsman.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The phrases "DNA coding for a promoter" in claim 1 and "DNA coding for the human platelet glycoprotein IIb" in claim 2 are unclear. The term "coded" refers to combinations of three consecutive nucleotides in a DNA molecule that control insertion of a particular amino acid in a protein. A "promoter" is a non-coding sequence at which transcription is initiated. Thus, the claims are confusion as to whether the DNA construct contains a DNA sequence "coding for a protein" or a DNA sequence that is a promoter. Clarification is required.

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4. Claim 3 recites the limitation "the cDNA" in line 2. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 4 recites the limitation "the first truncated intron" in line 1. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 4 also recites "inserted **additionally** into the FIX-cDNA" (emphasis added). The term "additionally" in this phrase implies that something else has been inserted into the FIX-cDNA. Thus, the claim is confusing as to whether and/or what else is inserted into the FIX-cDNA.
7. Claims 5-7 are indefinite because the relationship between the Factor IX that is expressed and the DNA construct that is transfected is unclear (is the Factor IX expressed from the DNA construct?). The examiner suggests amending the claim to include steps. In general, such steps could include transfecting the DNA construct, expressing the protein, and isolating the protein.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-3, and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hao et al. (Human Gene Therapy (July 1995) 6: 873-880) in view of Uzan et al. (J. Biol. Chem. (1991) 266(14): 8932-8939).

11. Hao et al. teaches a DNA construct for the expression of factor IX in a hematopoietic cell line (HL-60 cells; p. 877, Col. 2) comprising DNA coding for a blood coagulation factor (FIX) and a process of using the construct to express factor IX in a hematopoietic cell line (HL-60; see abstract). Hao et al. suggests using hematopoietic-specific promoters (p. 879, Col. 1, lines 27-28). Hao et al. also teaches induction of expression with PMA (clm 5-7) in HL-60 cells (p. 878, Table I).

12. Hao et al. does not teach specifically using the GPIIb promoter but does suggest using hematopoietic specific promoters to express factor IX in general.

13. Uzan et al. provides a characterization of the GPIIb promoter and concludes that the GPIIb promoter contains sufficient information to direct tissue specific expression and suggests that this promoter can be used to target expression of heterologous genes in megakaryocytes (hematopoietic cells; see p. 8932, 1st paragraph of intro. And p. 8938, Col. 2, last two lines).

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14. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the DNA construct for the expression of factor IX as taught in Hao et al. such that it contained the hematopoietic specific promoter, GPIIb, characterized in Uzan et al. and use the DNA construct in a method of making factor IX as taught in Hao et al. One would have been motivated to make such a DNA construct and use it to produce Factor IX because Hao et al. teaches that DNA constructs comprising a hematopoietic-specific promoter and a sequence coding for Factor IX are desirable for potential use in transfecting hematopoietic cells to be used in the treatment of hemophilia because they are more readily obtained than other cells, such as hepatocytes (see p. 878, Discussion, paragraph bridging Col. 1 and 2). Thus, it appears that the claims are unpatentable over the prior art.

15. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hao et al. and Uzan et al. as applied to claim 1 above, and further in view of Kurachi et al. (J. Biol. Chem. (1995) 270(10): 5276-5281; cited in IDS of Paper No. 2).

16. The teachings of Hao et al. and Uzan et al. have been described above.

17. Hao et al. and Uzan et al. do not teach a DNA construct wherein Intron 1 of the human factor IX gene is inserted into the factor IX cDNA.

18. Kurachi et al. teach a construct encoding human factor IX wherein the first intron of human factor IX is inserted into the factor IX cDNA and wherein the Intron I sequence enhances transgene expression by protecting spliceosome complexes from random degradation (see abstract and figure 2, p. 5278).

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19. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to add an Intron I sequence of factor IX to a DNA construct comprising a tissue specific promoter and a sequence coding for factor IX as taught and suggested in Hao et al. and Uzan et al. One would be motivated to insert the Intron I sequence into the factor IX cDNA because, as Kurachi et al. teach, the first intron of Factor IX functions to enhance gene expression. Thus, it appears that the claims are unpatentable over the prior art.

Conclusions

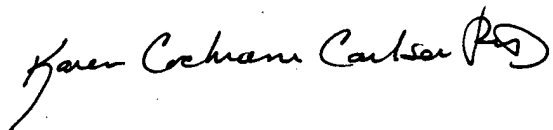
No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Mon. & Thurs., 8am-5:30pm and Tues. & Wed. 9 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Holly Schnizer
August 16, 2001


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER
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